

REMARKS

The Office Action of October 30, 2003 presents the examination of claims 83-120. The present paper amends claims 83-85, 89, 90, 92, 96 and 97, and adds new claim 121. Claims 83-121 are pending.

Sequence compliance

The Examiner has required the filing of a Sequence Listing.

A printed Sequence Listing in the German language appears to have been filed as part of the application upon entry into the National Stage on November 2, 1998. See the attached copy of the first page of the application transmittal papers.

A paper copy of a Substitute Sequence Listing in the English language is submitted herewith. The Computer Readable Form of the Sequence Listing is filed on diskette herewith and is contained in the file 2004-04-30 0690-0110P.ST25. This CRF **is identical to the printed copy of the Sequence Listing concurrently filed**, except that it lacks formatting.

The Sequence Listing filed with this paper does not introduce any new matter into the application. The sequence of SEQ ID NO: 1 is provided in the original application in Figure 10A-10C.

A copy of the Notice to Comply with Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures is attached hereto.

Amendment to recite the Sequence Listing Identifier

An amendment to append the substitute Sequence Listing filed herewith is made to the specification above.

The paragraph describing Figure 10A-10C at page 15 of the specification has been amended, by Applicants' paper filed December 4, 2001, to recite the SEQ ID NO: 1 of the present Sequence Listing.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 83, 84, 88-92 and 95-120 are rejected under 35 U.S.C. § 112, second paragraph, as alleged indefinite for various recitations as set forth on pages 3-4 of the Office Action.

As to claims 83 and 91, these claims are amended to clarify the intention that the ITR and packaging signals are obtained from a single viral source. With respect to the location of the ITR sequences, the term "terminal repeat sequences" makes clear that the ITRs are located at the ends of the claimed nucleic acids molecule. This is also well-known to the skilled artisan. Furthermore, the skilled artisan recognizes that the precise location of a packaging signal is not required; generally only the presence of a packaging sequence, without regard to specific location, is required for packaging of a nucleic acid into a viral coat. Such is also well-known to the artisan of ordinary skill. The term "operative linkage" as applied to the ITR and the

packaging signal also makes clear that only functional embodiments are encompassed by the claims.

In claims 83 and 91, the article has been changed from "the" to "a" to provide antecedent basis for the recitation of "a nucleic acid sequence to be expressed."

In claim 84, the nucleotide residue representing the start of transcription of the MLC-2 gene is now indicated with reference to SEQ ID NO: 1. The Examiner should note the nucleotide indicated as "+1" in Figure 10A-10C. New claim 121 recites a part of SEQ ID NO:1 as a promoter sequence.

In claim 85, "m.u." has been replaced by "map units" and "Ad5" has been replaced by "adenovirus type 5"; see the first paragraph on page 13 of the English translation of the specification.

In claims 89, 90, 96 and 97, "proteinaceous gene product" has been replaced by "protein" as suggested by the Examiner.

Claim 92 has been amended to clarify that a "CSS element" has a sequence of a particular portion of SEQ ID NO: 1. The Examiner may refer to the relevant portion of Figure 10A.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejects claim 85 under 35 U.S.C. § 112, first paragraph, requiring deposit of the vector pADRSV β -gal. Applicants have taken this requirement under advisement. The Examiner is

respectfully requested to hold this issue in abeyance until allowable subject matter is found in the application.

Rejections over prior art

Claims 83, 84, 86-89, 104, 105, 110, 111, 116 and 117 are rejected under 35 U.S.C. § 102(a) as anticipated by Rothmann et al. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Applicants submit herewith certified English translations of the priority applications DE 195 42 838.2 and DE 196 40 630.7. Applicants submit that these translations are sufficient to antedate the Rothmann et al. reference and overcome the instant rejection.

Claims 83, 84, 86-90, 98-100, 104-106, 110-112 and 116-118 are rejected under 35 U.S.C. § 103(a) as unpatentable over Rothmann et al. in view of Sukhatme. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

As the Rothmann reference is overcome as prior art, Sukhatme alone is insufficient to establish *prima facie* obviousness of the presently claimed invention. Accordingly, the instant rejection should be withdrawn.

The present application well-describes and claims patentable subject matter. The favorable action of allowance of the pending

claims and passage of the application to issue is respectfully requested.

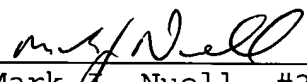
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell (Reg. No. 36,623) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), Applicants respectfully petition for a three (3) month extension of time for filing a response in connection with the present application. The required fee of \$475.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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By 
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0690-0110P

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Attachment(s): Sequence Listings (paper copy and floppy disk)
A copy of the Notice to Comply with Requirements
DE 195 42 838.2 with English translation
DE 196 40 630.7 with English translation

(Rev. 02/12/2004)